

Monday, November 9, 2015		
Time	Topic	Speaker(s)
7:30 AM	Registration	
8:00 – 8:05 AM	Welcome	Robert Nelson
8:05 – 8:15 AM	Introductory Remarks https://youtu.be/jymg59f9O94	Luciana Borio
8:15 – 8:45 AM	Opening Presentation	Ian Crozier
First Panel: The Challenges of Developing New Treatments for Life-Threatening Diseases: From HIV-AIDS to EVD		
<i>Abstract:</i> This session will explore the challenges of conducting clinical trials in the context of an emerging, and poorly understood fatal infectious disease. The discussion will cover issues from HIV-AIDS to EVD, including the tension between the need for controlled clinical trials and the desire for access to investigational treatments.		
8:45 – 9:15 AM	Presentation: Studying effects of medical treatments: the need for randomized clinical trials https://youtu.be/LYGI5LThpTo	Susan Ellenberg
9:15 – 9:45 AM	Presentation: Right of Access to Experimental Treatments (provisional title) https://youtu.be/JyVpJu97PLw	Udo Schuklenk
9:45 – 10:15 AM	Presentation: Lessons Learned From HIV-AIDS (provisional title) https://youtu.be/NdL6ALHjpKt	Martin Hirsch
10:15 – 10:45 AM	Morning Break	
10:45 AM – 11:45 PM	Moderated Panel Discussion (with Audience Q&A) https://youtu.be/R9xIGLGIhvQ	Moderator: Sean Philpott-Jones
	Panel Members: Susan Ellenberg; Udo Schuklenk; Martin Hirsch; Gregg Gonsalves; Annick Antierens ; Mosoka Fallah; Ian Crozier	
11:45 - 12:45 PM	Lunch	
12:45 – 1:00 PM	Reports: WHO R&D Blueprint plus outcomes of London meeting on generating evidence for epidemic infectious diseases https://youtu.be/30uenKBryo0	David Wood
1:00 – 1:40 PM	Presentation: Perspectives on clinical trials in emergency situations; decoding language and unveiling assumptions https://youtu.be/Zt2EtpSISsc	Steven Goodman
1:40 – 2:00 PM	Commentary https://youtu.be/sb7wlZ4kgiY	Alex London
2:00 – 2:30 PM	Audience Q&A https://youtu.be/SDp_Co8Xsbg	Moderator: Lisa LaVange
2:30 – 3:00 PM	Afternoon Break	
Second Panel: Case Studies in Designing Clinical Trials for Emerging Infectious Diseases		
3:00 – 3:20 PM	Vector-borne Diseases https://youtu.be/F_JeEvly900	Charles Hoke
3:20 – 3:40 PM	MERS-CoV https://youtu.be/4lx-FORc4EU	James King

3:40 – 4:00 PM	Pandemic Influenza https://youtu.be/ZsYd8dwDt_I	Fred Hayden
4:00 – 4:50 PM	Moderated Panel Discussion (with Audience Q&A) https://youtu.be/6zGpbSstvPY	Moderator: Chris Woods
	Panel Members: Charles Hoke; James King; Fred Hayden; Fatorma Boley	
4:50 – 5:00 PM	Closing Remarks	

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Parallel Session: Clinical Trial Designs for Preventive Interventions (Vaccines)		
8:00 – 8:20 AM	Clinical Trial Design #1: PREVAIL (NIAID) https://youtu.be/2fp2CrQnU4I	James Neaton
8:20 – 8:30 AM	Clarifying Questions from Panel Members	
8:30 – 8:50 AM	Clinical Trial Design #2: STRIVE (CDC) https://youtu.be/2nZpichTy1w	Anne Schuchat
8:50 – 9:00 AM	Clarifying Questions from Panel Members	
9:00 - 9:20 AM	Clinical Trial Design #3: Guinea ring vaccination cluster-randomized trial https://youtu.be/GV3Ho7mfpFQ	Ana Maria Henao-Restrepo/Ira Longini
9:20 – 9:30 AM	Clarifying Questions from Panel Members	
9:30 – 10:00 AM	Break	
10:00 – 11:30 AM	Moderated Panel Discussion https://youtu.be/On8BTImQ8Nw	Moderator: Robert Daum
		Rapporteur: Pamela McInnes
	Panel Members: Jim Neaton; Anne Schuchat; John-Arne Rottingen; Estelle Russek-Cohen; Alex London; Rebecca Grais; Mark Kieh; Kader Konde	
Panel Discussion Question 1: Scientific	Please discuss the effectiveness (e.g., data quality and interpretability) and efficiency (e.g., speed, sample size) of the different study designs with respect to establishing efficacy and assessing safety.	
Panel Discussion Question 2: Ethical	How did non-scientific (ethical) considerations such as the community's acceptance of randomization to a non-experimental control arm, with or without a placebo (i.e., blinding), and/or the adequacy of the local clinical or preventive care influence the choice of study design? Did these considerations compromise the ability of the study design to assess efficacy and/or safety?	
Panel Discussion Question 3: Practical	How did practical concerns such as obtaining the necessary regulatory and ethical approvals, engaging with the community, or not interfering (aligning) with the outbreak response (including staff safety), influence the choice of study design? Did these concerns compromise the ability of the study design to assess efficacy and/or safety?	
Panel Discussion Question 4: Future Outbreaks	How applicable are these study designs (and the considerations that went into the choice of those designs) to other emerging infectious diseases that may occur in unknown locations in the future?	
11:30 AM – 12:00 noon	Audience Questions	

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Parallel Session: Clinical Trial Designs for Therapeutic Interventions		
8:00 – 8:20 AM	Clinical Trial Design #1: NCT02363322 (NIAID) https://youtu.be/s8AknOHf72c	Mike Proschan
8:20 – 8:30 AM	Clarifying Questions from Panel Members	
8:30 – 8:50 AM	Clinical Trial Design #2: Multi-stage Approach https://youtu.be/Pqgu0Lg-KEE	Peter Horby/John Whitehead
8:50 – 9:00 AM	Clarifying Questions from Panel Members	
9:00 -9:20 AM	Clinical Trial Design #3: Adaptive Randomized Trial https://youtu.be/HlpdLykRhQ0	Scott Berry
9:20 – 9:30 AM	Clarifying Questions from Panel Members	
9:30 – 10:00 AM	Break	
10:00 – 11:30 AM	Moderated Panel Discussion https://youtu.be/jKOkxotcSaA	Moderator: Tom Moore
		Rapporteur: Robert Walker
	Panel Members: Mike Proschan; Peter Horby/John Whitehead; Dave Hoover; Ed Cox; Sean Philpott-Jones; Annick Antierens; Wiltshire Johnson; Luke Bawo; Andre Kalil	
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Tuesday, November 10, 2015		
12:00 – 1:00 PM	Lunch	
Panel: Summary of the Parallel Sessions		
1:00 – 1:20 PM	Report of “Preventive” Session https://youtu.be/67a_lAz--EM	Rapporteur: Pamela McInnes
1:20 – 1:40 PM	Report of “Therapeutic” Session https://youtu.be/XoVwDUwm-BQ	Rapporteur: Robert Walker
1:40 – 2:30 PM	Moderated Discussion of Reports https://youtu.be/ZSNe-U-5R_s	Moderator: Udo Schuklenk
	Panel Members:	Stephen Kennedy; Abdoul Habib Beavogui; (other panelists pending)
2:30 – 3:00 PM	Break	
Closing Panel: Building on the Past, Looking Towards the Future		
3:00 – 3:20 PM	Presentation https://youtu.be/FrxVnY_Gazo	Richard Hatchett
3:20 – 3:40 PM	Presentation https://youtu.be/EZzOW7LLtik	Adel Mahmoud
3:40 – 4:40 PM	Closing Moderated Panel Discussion https://youtu.be/lfw1a4SMAO0	Moderator: John-Arne Rottingen
	Panelists:	Elizabeth Higgs; David Sumo; Mosoka Fallah; Kader Konde; (other panelists pending)
4:40 – 5:00 PM	Closing Remarks https://youtu.be/qiQHG2146zM	Luciana Borio